CLAIMS

1. A method for determining the allergic status of an individual comprising:

a. exposing a cell-line, which is a secretor variant of mast cell or basophil lineage and is transfected with a moiety capable of binding human IgE, to a sensitizing agent;

b. challenging the cell-line with at least one allergen; and

c. determining the release of mast cell or basophil mediators in response to said challenge.

2. A method according to Claim 1 wherein said mast cell-line is an RBL-2H3 cell-line which is transfected with the α-chain at least of the human high-affinity receptor for IgE.

3. A method according to Claim 1 wherein said sensitizing agent is human IgE.

4. A method according to any preceding Claim wherein said cell-line is pre-incubated in a solution containing a radio active marker.

5. A method according to Claim 4 wherein said marker is tritiated histamine.

6. A method according to Claim 4 wherein said marker is ^{14}C arachadonic acid.

7. A method according to Claims 1-3 wherein spectrophotometric means is used to determine release of mediators.

8. A method according to Claims 1-6 wherein said release of mediators is determined using an immunoassay technique.

9. An assay kit for determining the allergic status of an individual comprising:

a. a cell-line which is a secretor variant of a mast cell-line or a basophil cell-line and is transfected with a moiety capable of binding human IgE;

b. a test allergen; and

c. means necessary to determine the absence or presence of an immune response.

10. An assay kit according to Claim 9 wherein the cell-line is an RBL-2H3 cell-line which is transfected with the alpha-chain at least of the human high-affinity receptor for IgE.

11. An assay kit according to Claims 9 or 10 wherein there is further provided a pre-determined amount of radio active marker.

12. An assay kit according to Claim 11 wherein said marker is tritiated histamine.

13. An assay kit according to Claim 11 wherein said radio active marker is arachadonic acid.

14. An assay kit according to Claims 9 or 10 wherein there is provided a chromogen means for measuring release of mediators.

15. An assay kit according to Claims 9-13 wherein there is provided immunoassay means for measuring release of mediators.

16. A method for determining the potential irritancy or allergenicity of a pre-selected substance comprising:

a. exposing a mast cell-line and/or basophil cell-line to said substance in the absence of ~~a sensitizing agent~~ A sensitizing agent human IgE; and

b. then determining the release of mast cell and/or basophil cell mediators in respons to said exposure.

17. A method for determining the potential irritancy or allergenicity or a pre-select substance comprising:

a. exposing a cell-line, which is a secretor varient of mast cell or basophil liniage and is transfected with a moiety capable of binding human IgE, to said substance in either the absence or presence of a sensitising agent; and

b. then determining the release of mast cell and/or basophil cell mediators in response to said exposure.

18. A method according to Claim 16 or 17 wherein said cell-line is a high-secretor variant.

19. A method according to Claim 16, 17 or 18 wherein the cell-line is a secretor variant of RBL-2H3.

20 A method according to Claims 16-19 wherein said cell-line is pre-incubated with a marker.

21 A method according to Claim 20 wherein the marker is tritiated 5-hydroxytryptamine or histamine.

22. A method according to Claim 20 wherein the marker is ^{14}C arachadonic acid.

23. A method according to Claims 16-19 wherein the method comprises exposing said cell-line to a chromogen which changes colour as a result of the presence of an immunogenic reaction.

24. A method according to Claims 16-22 wherein the method comprises exposing said cell-line to an immunoassay means for measuring release of mediators.

25. A therapeutic composition comprising a substance containing a C-terminal lysine residue for the inhibition of mediator release in an allergic reaction.

26. The use of a substance containing a C-terminal arginine residue for the manufacture of a medicament for the inhibition of mediator release from activated mast cells or basophil cells in an allergic reaction.

27. The use of a substance comprising a substrate or inhibitor of a mast cell of basophil cell endoprotease secreted in response to activation of the mast cell or basophil cell for the manufacture of a medicament for the treatment of an allergic reaction.

28. A therapeutic composition accordinfg to Claim 27 wherein said protease is a serine endoprotease.

29. A therapeutic composition according to Claim 27 wherein said substrate is p-toluenesulphonyl-L-arginine methyl ester (TAME).

30. A therapeutic composition according to Claim 27 wherein the inhibitor is a human IgE-derived pentapeptide (HEPP).